

Washington State Rapid HIV Testing Information

Previous Title: Washington State OraQuick® Rapid HIV Testing and Counseling Guide

This document is consistent with Washington State rules adopted by
the Washington State Board of Health as of June, 2005.

*Use of trade names and commercial sources is for identification only
and does not imply endorsement by the Washington State Department of Health*



October, 2005

Credits

Mark Alstead, Frank Chaffee, Karolyn Luzzi, Lenore Morey
Gail Neuenschwander, Barbara Schuler, Dennis Worsham

For more information, contact the Washington State HIV Prevention Program:

Claudia Catastini, MA
claudia.catastini@doh.wa.gov
(360)-236-3422

HIV Prevention & Education Services
Washington State Department of Health,
PO Box 47840
Olympia, Washington 98504-7840

TABLE OF CONTENTS

NOTICE	1
AGENCY LICENSE REQUIREMENTS	2
TESTING PERSONEL LICENSE REQUIREMENTS	3
SPECIMEN COLLECTION OVERSIGHT/SUPERVISION	4
CONFIDENTIALITY	5
SPECIAL CONSIDERATIONS	6
Preliminary Reactive Results	
No-Shows for Confirmatory Test Results	
Age of Consent	
HIV RISK ASSESSMENT	7
HIV TESTING INFORMATION	8
INFORMED CONSENT	9
HIV COUNSELING	10
HIV REPORTING	11
PARTNER COUNSELING AND REFERRAL	12
WASHINGTON STATE RECOMMENDATIONS	13
Low Prevalence Testing with Whole Blood Fingerstick	
Confirmatory Testing: HIV-1 or HIV-2?	
Confirmatory Test Results	
Venipuncture Whole Blood Specimen: Laboratories Only	
APPENDICES	16
Appendix A: Implementation Sequence	
Appendix B: Agency Consideration Worksheets	
Appendix C: HIV Testing and Counseling Flow-chart	

NOTICE

Agencies implementing rapid testing should refer to the product manufacturer's material (product inserts, manufacturer's Quality Assurance Guidelines, and associated protocols) to develop their programs.

Agencies implementing OraQuick ADVANCE Rapid HIV-1/2 Antibody Testing, should refer to the manufacturer's document: *OraQuick ADVANCE Rapid HIV-1/2 Antibody Test ADOPTER PROTOCOL*.

This guide augments the manufacturer's materials by providing information that is specific to Washington State rules and regulations. Agencies should use the manufacturer's materials to develop their rapid testing policies and procedures, and use the information in this guide to ensure that their programs follow Washington State rules and law.

For more information about Washington State rules and laws governing HIV testing, contact Claudia Catastini at Washington State Department of Health, HIV Prevention and Education services (360) 236-3422.

AGENCY LICENSE REQUIREMENTS

The Washington State Medical Test Site Law, Revised Code of Washington (RCW) Chapter 70.42, requires that all sites performing clinical laboratory testing obtain a state Medical Test Site (MTS) license.

All entities conducting waived rapid HIV testing must obtain an MTS license (Category: Certificate of Waiver). The Washington State MTS license takes the place of a federal CLIA certificate.

If the site already has a MTS license covering other laboratory testing that is being performed, waived rapid HIV testing can be performed under that license. However, the site must still inform the Department of Health (at the address below) that this testing will be added to their existing license.

For more information, to inform the department that rapid testing will be added to an existing license, or to obtain a license application, contact:

Department of Health
Office of Laboratory Quality Assurance
1610 NE 150th St.
Shoreline, WA 98155

Phone: (206) 361-2802
Website: www.doh.wa.gov/lqa/htm

The fee for a two-year Certificate of Waiver license is \$150.00. A fee statement will be sent once the license application has been received. If the site already has a MTS license that covers other laboratory tests, there will not be an additional fee for adding the rapid HIV test.

TESTING PERSONNEL LICENSE REQUIREMENTS

Whole Blood Specimen Collection

In Washington State, the following three categories of personnel have the authority to collect blood specimens through fingersticks and venipuncture:

- some licensed health care professionals (whose scopes of practice allow it);
- certified health care assistants; and,
- sexually transmitted disease case investigators.

Licensed Health Care Professionals

The scope of practice of some licensed health care professionals (including physicians and nurses) allows those licensed individuals to collect blood specimens by fingerstick and venipuncture. Therefore, no additional licensing is required to conduct blood specimen collection for rapid testing.

Certified Health Care Assistants

The Washington State Health Care Assistants Law, Chapter 18.135 RCW, requires certification of all unlicensed individuals who may be administering skin tests, subcutaneous, intradermal, intramuscular, and intravenous injections, or performing minor invasive procedures to withdraw blood and/or hemodialysis. Fingerstick, venous and capillary collection of blood specimens are procedures that require certification as a health care assistant for all unlicensed individuals (exception to this rule: sexually transmitted disease case investigators, see section below).

To obtain information regarding the Health Care Assistant certification, contact:

Health Professions Quality Assurance
Customer Service Center
PO Box 47865
Olympia, WA 98504

Phone: (360) 236-4700
Technical Assistance: (360) 236-4942
Email: hpga.csc@doh.wa.gov

Sexually Transmitted Disease Case Investigators

Sexually transmitted disease case investigators are individuals who:

- 1) are employed by public health authorities;
- 2) have been trained by a physician in proper specimen collection procedure; and,
- 3) possess a statement signed by the instructing physician that this training has been successfully completed.

Sexually transmitted disease case investigators are authorized to perform both venipuncture and fingersticks for the purpose of specimen collection for sexually transmitted disease tests (RCW 70.24.120). No additional licensing is required.

Oral Fluid Specimen Collection

There are no Washington State certification or licensing requirements for oral fluid specimen collection.

SPECIMEN COLLECTION OVERSIGHT/SUPERVISION

Whole Blood Specimen Collection

In Washington State, the supervision and oversight requirements for those with authority to collect blood specimens vary as follows:

Licensed Health Care Professionals

For those physicians whose licenses allow for blood specimen collection by fingerstick and venipuncture, no additional supervision or oversight is needed.

RNs and LPNs do need oversight of at least a written order or protocol from a physician.

Certified Health Care Assistants

Certified health care assistants are individuals who have been certified as health care assistants through the delegation of a licensed health care professional. Certified health care assistants who perform blood specimen collection require blood specimen training and supervision by a licensed health care practitioner.

For the rapid test fingerstick, the supervisor need not be physically present, but must be immediately available. "Immediately available" means in immediate contact for consultation by any means, electronic, or otherwise, within a short period of time. Immediate cell phone contact fulfills this requirement. In addition to having this consultation available, policies and procedures should be in place which direct the health care assistant to call "911" for emergency assistance in the event of an adverse reaction to a fingerstick.

To perform a venipuncture, health care assistants must have the supervising practitioner on the premises and immediately available for consultation and assistance during the procedure to withdraw blood (RCW 18.135.020; WAC 246-826-030). Staffing and supervision policies and procedures for each test site should reflect this.

Sexually Transmitted Disease Case Investigators (DIS)

Sexually transmitted disease case investigators are authorized to perform this specimen collection without supervision (RCW 70.24.120).

Oral Fluid Specimen Collection Supervision

There are no Washington State supervision requirements for oral fluid specimen collection.

CONFIDENTIALITY

Confidentiality of records, personal information gathered from clients, HIV testing, and test results, is of the utmost importance.

All client information and records must be maintained using an approach consistent with Washington law (RCW 70.02 and RCW 70.24) and, if applicable, the Privacy and Security Requirements promulgated by the federal government in the Health Insurance Portability and Accountability Act (HIPAA). Client information must be kept strictly confidential and records should be managed and stored in a secure manner.

Agencies providing rapid HIV testing must develop confidentiality policies and procedures that will prevent unauthorized persons from learning information shared in confidence. Confidential information includes any material, whether oral or recorded in any form or medium that identifies (or can readily be associated with the identity of) a person and is directly related to their health and care. All information relating to an individual's HIV/AIDS status is protected under medical confidentiality guidelines and legal regulations (RCW 70.24) (WAC 246-100). In recognition of the very sensitive nature of these conditions, medical record protection for HIV and AIDS, like those for substance abuse and mental health, are protected more rigorously than other medical information.

Minimum professional standards for any agency handling confidential information should include providing employees with appropriate information regarding confidentiality guidelines and legal regulations (RCW 70.24, RCW 70.02, and where applicable, the federal HIPAA privacy regulations).

All staff involved in HIV testing and counseling activities with access to testing results and counseling information should sign a confidentiality statement acknowledging their awareness and understanding of: 1) the legal requirements under state and federal law not to disclose HIV/AIDS information, and 2) the legal and agency consequences of such a disclosure.

SPECIAL CONSIDERATIONS

Providing Preliminary Reactive Results

In Washington State, a preliminary reactive rapid HIV antibody test cannot be used to diagnose HIV infection. Confirmatory testing must be conducted before diagnosing HIV infection.

When informing a patient of preliminary reactive results, Washington State rules (WAC 246-100-207) require that you:

- 1) explain the meaning of reactive screening test result in simple terms, avoiding technical jargon;
- 2) emphasize the importance of confirmatory testing and schedule a return visit for confirmatory test results; and
- 3) underscore the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing.

No-Shows for Confirmatory Results

For those sites that offer anonymous rapid testing, counselors should both offer and *strongly encourage* **confidential** confirmatory testing. Confidential confirmatory testing will assure that clients receive confirmatory results, partner counseling and referral services, and referral into appropriate case management and care services.

For clients that choose to remain anonymous for confirmatory testing, the Washington State and the CDC recommend that counselors obtain detailed locating information on the clients so that they can be contacted (if they fail to return for their results), notified of their results, and encouraged to come in for care and follow-up. Counselors must explain this rationale for collecting locating information to the client so the client understands that, although they tested anonymously, the locating information will allow for notification of their results if they do not return. If anonymous clients (who provided locating information) do not return for results, agencies should consult with local health department staff regarding locating and notifying clients.

For those clients who agree to confidential confirmatory testing, Washington State rules require agencies to refer locating information on confidential clients (that do not return for their positive HIV results) to local health department staff to locate and notify them of their results (WAC-246-100-207).

Age of Consent

The same laws regarding age of consent for standard HIV testing apply for rapid HIV testing. A person must be 14 years of age to provide independent consent for an HIV test (RCW 70.24.110).

Note: it is not recommended to use OraQuick® *ADVANCE* on persons under the age of 12, as no clinical data is available demonstrating the performance of OraQuick® *ADVANCE* on persons under the age of 12.

HIV RISK ASSESSMENT

Washington State law requires that individuals who are tested for HIV receive an individualized risk assessment (WAC 246-100-209).

A client's individual HIV risk can be determined through risk screening based on self-reported behavioral risk and clinical signs or symptoms. Behavioral risks include injection-drug use or unprotected intercourse with a person at increased risk for HIV. Clinical signs and symptoms include those suggestive of HIV infection and other STDs.

Behavioral risks can be identified either through open-ended questions by the provider, or through screening questions (i.e., a self-administered questionnaire). "What are you doing now or what have you done in the past that you think may put you at risk of HIV infection?" is an example of an open-ended question.

Examples of screening questions are:

"Since your last HIV test (if ever) have you:

- injected drugs and shared equipment (e.g., needles, syringes, cotton, water) with others?
- had unprotected intercourse with someone that you think might be infected?
- had unprotected vaginal or anal intercourse with more than one sex partner?"

Note: This is not a comprehensive listing of risk screening questions.

See Appendix C for a flowchart of the State requirements associated with HIV testing.

HIV TESTING INFORMATION

Washington State rules require that providers conducting HIV testing deliver information about HIV and HIV testing to clients. This information must be culturally, linguistically, developmentally, and medically appropriate, and include:

- the benefits of learning HIV status and the potential dangers of the disease;
- a description of the ways HIV is transmitted and how it can be prevented;
- the meaning of the test results and the importance of obtaining test results; and,
- as appropriate, the availability of anonymous HIV testing and the differences between anonymous testing and confidential testing.

In addition, clients tested with rapid HIV tests should be:

- advised that their rapid test results will be available during the same visit.
- informed that confirmatory testing is needed if the rapid test result is reactive.

This information can be provided either in a face-to-face meeting with a counselor or in a pamphlet, informed consent form, brochure, or video. If a pamphlet, informed consent form, brochure, or video is used to convey this information, the counselor should also check in with the client to assure s/he understands the information.

Information describing the rapid test and the window period should be clear, concise, and consistent, to avoid both individual client confusion and mixed and unclear messages about the rapid test process disseminating into the community. For example:

RAPID TEST: *“The rapid test is a same-day test. You will receive your results today.”*

WINDOW PERIOD: *“This test looks for HIV antibodies. It can take up to 3 months to develop these antibodies. This test will tell you whether or not you were infected as of 3 months ago. If you engaged in risk behavior during the last 3 months, and you became infected, that **may not** show up on this test. You’ll need a test a full 3 months from the last time you put yourself at risk to be sure.”*

If a person has been previously tested they can decline receipt of information.

Note: The OraQuick® ADVANCE package insert also requires that individuals being tested with the rapid test **must** receive the “Subject Information” pamphlet prior to specimen collection.

See Appendix C for a flowchart of the State requirements associated with HIV testing.

INFORMED CONSENT

As with the standard HIV test, Washington State law requires that providers conducting HIV tests obtain or ensure explicit verbal or written informed consent for HIV testing.

This verbal or written consent must be:

- obtained **prior** to performing the test, and
- **documented.**

Note: Washington State law does not require that the consent be in writing. Therefore, it is an option for test sites to obtain verbal consent. Verbal consent is often used in anonymous testing situations. If verbal consent is used, procedures and protocols should clearly identify and describe the process of how counselors will document the consent.

Because consent must be obtained *prior* to ordering or prescribing the test, counselors must obtain consent *before* they conduct the fingerstick or collect the oral fluid specimen and initiate the rapid test.

See Appendix C for a flowchart of the State requirements associated with HIV testing.

HIV COUNSELING

Pre-test Counseling

Washington State rules require that those conducting HIV tests must offer pre-test counseling to all persons at increased risk for HIV and to any person requesting it.

The person conducting the HIV test may provide the counseling or refer the client for counseling to another provider.

Those providing pre-test counseling must assess the individual's risk of acquiring and transmitting HIV by evaluating the individuals' risk behaviors and unique circumstances, and as appropriate:

- base counseling on the Centers for Disease Control and Prevention's Revised Guidelines for HIV Counseling, November 2001;
- assist the individual to set a realistic behavior change goal and establish strategies for reducing their risk of acquiring or transmitting HIV;
- provide appropriate risk reduction skills-building opportunities to support the behavior change goal; and,
- provide or refer for other appropriate prevention, support, or medical services.

Note: a person's refusal of pre-test counseling is not grounds for denying HIV testing.

Post-test Counseling

All clients who test positive for HIV must be provided with post-test counseling.

The provider testing the client can provide the post-test counseling or arrange for such counseling. Post-test counseling must be consistent with WAC 246-100-209 (1) and the CDC's Revised Guidelines.

In addition, those providing post-test counseling must also:

- inform the individual of HIV reporting requirements (unless the testing was anonymous);
- ensure compliance with partner notification requirements (WAC 246-100-072);
- develop a system to avoid documenting names of referred partners in the permanent record of individuals being counseled;
- offer referrals for alcohol and drug and mental counseling;
- provide or refer for medical evaluations including services to other bloodborne pathogens, antiretroviral treatment, HIV prevention and other support services, and tuberculosis screening.

Note: HIV Test Counseling requirements are in WAC 246-100-207 and WAC 246-100-209.

See Appendix C for a flowchart of the State requirements associated with HIV testing.

HIV REPORTING

In Washington State, AIDS has been reported since 1983, symptomatic HIV infection since 1987, and asymptomatic HIV infection since 1999.

Agencies providing confidential HIV testing should develop policies and procedures (including roles and responsibilities) to ensure the timely reporting of HIV cases to the local health department.

Note: Positive HIV results obtained through anonymous testing are not reportable.

Therefore, if an agency provides **only** anonymous testing, reporting is not required.

However, it is recommended that agencies offer and encourage confidential confirmatory testing in order to ensure that clients receive confirmatory results, PCR services, and referral into appropriate case management and care services.

State laws and health department security and confidentiality rules protect the identity of persons reported with HIV or AIDS. Anyone who violates these confidentiality laws may be found guilty of a gross misdemeanor and may be subject to action for reckless or intentional disclosure up to a fine of \$10,000 for each infraction or actual damages, whichever is greater (RCW 70.24.080, RCW 9A.20.021, RCW 70.24.084).

Case report information for individual patients can only be shared on a “need to know” basis. Case reports must be kept in locked rooms with access limited to authorized personnel who are trained in maintaining the confidentiality and security of these records.

For the address of the local health department in your county, assistance in developing a reporting policy, or information on HIV/AIDS reporting, call the state office:

Olympia: (360) 236-3419

Kent: (253) 395-6731

Toll free number: (888) 367-5555.

PARTNER NOTIFICATION

In Washington State, the rules for partner notification apply when a test is *confirmed positive*.

Therefore, with rapid testing, it is not necessary to discuss partner notification at the preliminary reactive rapid test result session.

Instead, providers must ensure compliance with the rules for partner notification at the post-test (confirmed) positive counseling session (WAC 246-100-072).

In Washington State, public health is responsible for providing partner notification services to the infected client and exposed partners.

It is also possible for providers to assist clients with partner notification; however, this assistance must be conducted according to CDC guidance.

For more information about partner notification requirements, call Claudia Catastini, at the State Department of Health's HIV Prevention Office at (360) 236-3422.

WASHINGTON STATE DEPARTMENT OF HEALTH RECOMMENDATIONS

Low Prevalence Testing with Whole Blood Fingerstick

Although rapid HIV tests can be highly accurate, as with any screening test, a risk of false results exists. In order to minimize this risk, Washington State Department of Health recommends, that whenever practical, whole blood fingerstick specimens are used for OraQuick® ADVANCE HIV-1/2 rapid testing, especially in populations with low HIV prevalence (less than 1%).

This recommendation is based on: 1) the difference between the sensitivity of OraQuick® ADVANCE testing of fingerstick whole blood specimens and oral fluid specimens; 2) the decrease in the positive predictive value of rapid HIV screening with low prevalence; and 3) the low prevalence of HIV in most populations in Washington State.

The sensitivity of a screening test is the probability that the test result will be reactive if the specimen is a true positive. The sensitivity of the OraQuick® ADVANCE for fingerstick whole blood is slightly higher (99.6) than that for oral fluid (99.3). The higher sensitivity for fingerstick whole blood means that the risk of false positives (test result is positive; but client is not infected) is *lower* with fingerstick whole blood than for oral fluid.

In addition, the likelihood that a positive result is false *increases* as the prevalence of HIV within a setting *decreases* (i.e., the *less* HIV present in the population being tested, the *more likely* that a reactive result will be false).

The low prevalence of HIV in the State of Washington means that most testing sites will be serving client populations with less than 1% prevalence. In such cases, there is increased likelihood that reactive HIV tests will be false positives. For more information on test accuracy see: Appendix P, "Information on Test Accuracy."

Confirmatory Testing: HIV-1 or HIV-2?

OraQuick® ADVANCE HIV-1/2 screens for both HIV-1 and HIV-2 but a reactive result does not differentiate between the two. To confirm for HIV-1, an HIV-1 Western Blot is used. To confirm for HIV-2, an HIV-2 Western Blot is used.

In Washington State, the standard procedure is to conduct confirmatory testing for HIV-1. Because HIV-2 is extremely rare in Washington, most laboratories do not have the testing materials necessary to conduct HIV-2 confirmatory testing. Most laboratories will automatically conduct HIV-1 confirmatory testing only, unless requested otherwise.

Because OraQuick® ADVANCE HIV-1/2 screens for both HIV-1 and HIV-2, there is the potential to serve the unusual client who is at risk for HIV-2. In those rare cases where a client could be at risk for HIV-2 infection (i.e. unprotected sex or shared needles with someone from an African country) first ensure that the laboratory conducting the confirmatory testing is capable of conducting both HIV-1 and HIV-2 testing, and when requesting confirmatory testing, be sure to request that the laboratory conduct both types of confirmatory testing on the specimen.

Confirmatory Test Results

- 1) If the confirmatory test result is **negative**, the rapid HIV test was probably false positive. However; before concluding the rapid test was false positive, additional testing is recommended:
 - If the original confirmatory test specimen was a blood specimen, repeat the confirmatory test with a new blood specimen to rule out specimen mix-up.
 - If the original confirmatory test specimen was an oral fluid specimen, repeat the confirmatory test. For the repeat confirmatory test of an original oral fluid confirmatory test, a blood specimen should be used.
- 2) If the confirmatory test result is **indeterminate**:
 - If the original confirmatory specimen was a blood specimen, advise the client to return for repeat testing in one month.
 - If the original confirmatory specimen was an oral fluid specimen:
 - a) Repeat the confirmatory test using a blood specimen.
 - b) If the repeat blood specimen confirmatory test is also indeterminate, advise client to return for repeat testing in one month.
- 3) If confirmatory test result is positive, no further confirmatory testing is recommended.

Venipuncture Whole Blood Specimen: Laboratories Only

The testing of whole blood from venipuncture provides additional opportunities for exposure. Therefore, Washington State Department of Health recommends that unless a testing site has an established laboratory, whole blood from venipuncture should not be used in rapid testing programs.

APPENDICES

APPENDIX A: IMPLEMENTATION SEQUENCE

APPENDIX B: AGENCY CONSIDERATION WORKSHEETS

APPENDIX C: HIV TESTING REQUIREMENT FLOW-CHART

APPENDIX A: IMPLEMENTATION SEQUENCE

1. Determine if agency has capacity to implement rapid testing (see Appendix B).
2. Determine if rapid testing is right for proposed clients (see Appendix B).
3. Determine if rapid testing is right for the proposed venue (see Appendix C).
4. Get site MTS license (Category: Certificate of Waiver) license (see page 2).
5. Set-up monitoring systems:
 - specimen tracking
 - device tracking
 - processing logs
 - refrigeration logs
 - ambient temperature logs, etc.
6. Set-up records systems:
 - client charts; consent forms; results logs.
7. Set-up materials procurement, tracking, monitoring:
 - test kits and control kits
 - confirmatory specimen collection, labeling, and shipping
 - biohazardous waste storage
8. Set-up material storage:
 - dedicated refrigerator for controls (No lunches allowed!)
 - kits and other materials
9. Set-up biohazardous waste management and disposal system.
10. Set up bloodborne exposure management plan.
11. Set-up procedure for confirmatory testing and develop formalized relationship with a laboratory with appropriate documentation.
12. Set-up specimen transport system for confirmatory testing.
13. Set-up partner notification and referral system.
14. Set-up linkages and interagency agreements for appropriate medical and social referrals for comprehensive follow-up care of persons who have HIV infection.
15. Identify & train appropriate staff:
 - test kit technique
 - finger-stick and/or oral fluid specimen collection for rapid testing; whole blood venipuncture and/or OraSure oral fluid specimen collection for confirmatory testing
 - counseling
16. Set-up staff QA & supervision.
17. Verify Rapid Testing Program is ready for implementation:
 - staff are trained and competent
 - test kits work
 - policies and procedures are in place and function effectively
 - logistics for confirmatory testing are in place and function effectively
 - biohazardous waste handling is in place

APPENDIX B: AGENCY CONSIDERATION WORKSHEETS

Because implementation of rapid testing presents significant challenges, agencies should carefully consider whether or not this technology is appropriate for their agency; their clients; and, the venues in which they propose to use waived rapid testing.

When considering whether or not to implement rapid testing, agencies should ask the following questions:

- 1) Agency Capacity: **Does our agency have the capacity to provide rapid testing?**
- 2) Client Appropriateness: **Is rapid testing appropriate for the clients we plan to serve?**
- 3) Venue: **Is rapid testing appropriate for the venue we plan to use?**

The following pages of this section provide worksheets to assist agencies in answering the above questions.

Worksheet 1:

Does our agency have the capacity to provide rapid testing?

The following tool is designed to help agencies assess their capacity to provide rapid testing. The table is split into two columns. The first column (on the left) lists elements that are critical to the implementation of rapid testing. The second (empty column) on the right is for agencies to fill out with either a “Yes” or a “No”. Use a “Yes” if your agency has the capacity to accomplish the element as described on the referenced page in this document. Use a “No” if your agency does not have the ability to accomplish the element.

Each of the following agency capacity elements is critical to successful implementation of rapid testing. Therefore, an agency should only consider implementing rapid testing if they can fill out this table with a “Yes” for all of the following elements:

Element	Yes/No
Licenses	
1. Washington State Medical Test Site License (Category: Certificate of Waiver)	
2. If collecting blood specimens through fingerstick and/or venipuncture: a Health Care Professional License, Health Care Assistant Certification, or for Public Health staff, designation of Sexually Transmitted Disease Case Investigators	
Program Policies and Procedures in Place	
3. Training of Testing and Counseling Personnel	
4. Storage of Test Kits	
5. Maintenance and Timing of Conducting Controls	
6. Maintenance and Documentation of Temperature	
7. Fingerstick Whole Blood and/or Oral Fluid Specimen Collection	
8. Test Kit and External Quality Controls	
9. Confirmatory Specimen Collection	
10. Test Clean Up and Lab Safety	
11. Shipping confirmatory specimens that meet biohazardous material shipping and handling requirements	
12. Biohazardous Waste Management	
13. Test Result Documentation	
14. Bloodborne Pathogens Exposure Plan	
15. Partner Notification and Referral Services	
16. Referral to Care Services; Case Management; and other appropriate referrals	
17. Reporting of HIV Cases (after confidential Confirmatory Positive test result)	
18. Comprehensive Program Quality Control	

Medical Records	
19. Established Medical Records System (that meets state & federal confidentiality requirements) with Medical Records and Associated Protocols	
20. Consent Forms	
Trained Staff	
21. Staff trained to conduct rapid test; rapid test controls; fingerstick and/or oral fluid and/or venipuncture specimen collection	
22. Staff trained to conduct confirmatory specimen collection; testing documentation; and, shipping	
23. Staff trained to document temperatures; testing (kits and controls); and, results	
Staff with Appropriate Interest and Capacities for Rapid Testing	
24. Staff who have received training in HIV counseling and who are willing and able to provide test results to clients using the single-session model	
25. Staff who are familiar with WAC requirements for counseling & testing	
26. Staff who are willing and able to counsel with the additional counseling challenge of providing preliminary reactive - positive results	
27. Staff who are willing and able to perform appropriate specimen collection (fingersticks; venipuncture; oral fluid), run the rapid test and controls, collect confirmatory specimens, and handle biohazardous waste	
28. Staff who are willing and able to monitor the environment and run controls	
29. Staff who are willing and able to accomplish the significant record-keeping and documentation requirements	
Supervision Capacity	
30. For those programs that will utilize Certified Healthcare Assistants, licensed health care practitioner supervision on site for venipuncture blood specimen collection and in immediate contact for fingerstick blood specimen collection	
31. A clear supervisory structure (with delineated roles and responsibilities) to ensure responsibility for training and guidance, oversight of testing procedures, and coordination of program	
32. A supervisory structure with skills and capacities to ensure quality control	
Coordination; Collaboration; and Linkages	
33. Establish formalized linkages (with appropriate documentation) with a laboratory for confirmatory testing of preliminary positive rapid tests	
34. Arranged linkages (with appropriate interagency agreements) between testing program and appropriate medical care for medical follow-up care of persons who have HIV infection	
35. Formalized linkages (with appropriate policies, procedures, and interagency agreements) in order to assure PCRS	
36. Formalized linkages (with appropriate policies, procedures, and interagency agreements for referrals) with high-risk negative interventions and interventions for HIV infected clients	

Environment	
37. Refrigeration for Storing Controls	
38. Controlled Environment for storing kits within temperature parameters	
39. Controlled Environment for transporting kits (if outreach testing)	
Miscellaneous	
40. Cost of the controls is in alignment with the agency expenditure plan for testing	
41. Capacity and system to purchase and/or obtain test kits	
42. Capacity and system to purchase all supporting materials (fingerstick and/or oral fluid specimen collection, confirmatory specimen collection and shipping, biohazardous waste storage and transport, etc)	
43. If testing off-site, capacity to transport records confidentially	

Worksheet 2:

Is rapid testing appropriate for the clients we plan to serve?

The following tool offers questions that can guide an agency in assessing whether or not rapid testing is appropriate for the clients they plan to serve. The five elements in this chart are not critical for the successful implementation of rapid testing. However, in terms of serving client needs, they suggest where it would be most appropriate to implement.

Therefore, while an agency could choose to implement rapid testing even if its answers are all “No” for this chart, agencies should **only consider implementing rapid testing if they have at least one “Yes” on this chart.**

Element	Yes or No
1. <i>Client population has substantial non-return rates for HIV test results, especially if non-return rate is high for clients who test positive</i>	
2. <i>The conventional 1- to 2-week waiting period for results is a barrier to testing for a substantial number of clients.</i>	
3. <i>Conventional venipuncture is a barrier to testing for a substantial number of clients</i>	
4. <i>In clinics where blood specimen collection for STDs (including HIV) is in place, clients would prefer to have an additional fingerstick in order to receive HIV results quickly</i>	
5. <i>Client population requests rapid testing</i>	

Worksheet 3: Is rapid testing appropriate for the venue we plan to use?

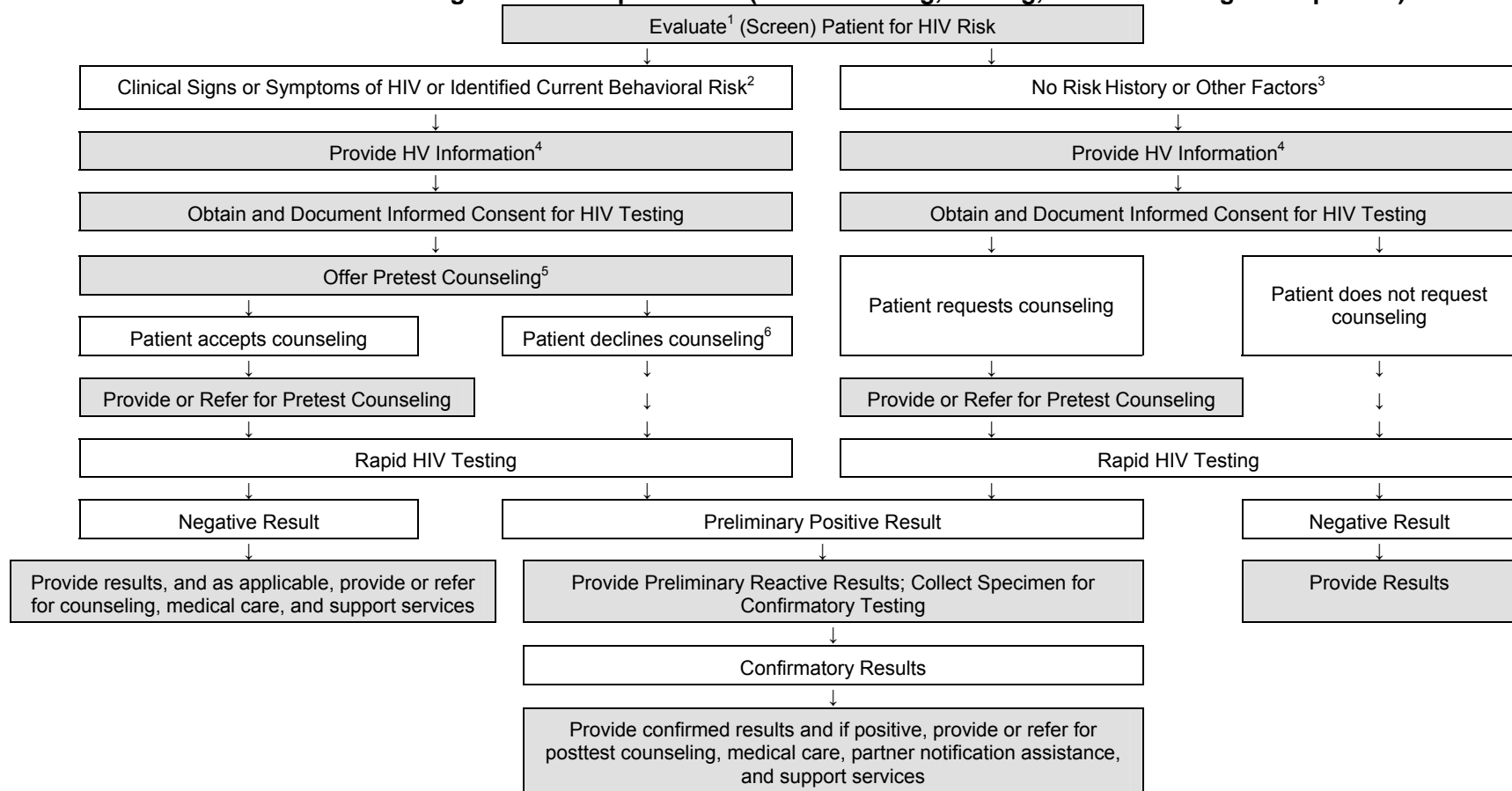
The following tool offers questions that can guide an agency in assessing whether or not rapid testing is appropriate for use in a planned venue. The last two *italicized* elements in this chart are not critical and necessary for the successful implementation of Rapid Testing.

Therefore, an agency could choose to implement rapid testing even if it answers “No” to these last two elements (13 and 14). However, elements 1-12 are critical and necessary for the successful implementation of rapid testing.

Agencies should only implement rapid testing in a site where they are able to fulfill each of the elements numbered 1 thru 12.

Element	Yes/No
1. There is an ability to maintain confidentiality of client services and patient records	
2. The site has the capacity to handle client flow and potential increase in client demand	
3. The site has a place for clients to wait and/or sign up prior to testing, and, when applicable, there is a place for clients to wait to receive results	
4. There is enough private space for testing and counseling	
5. There is an ability to maintain stable temperatures for testing (between 59 & 99 degrees)	
6. The site has appropriate level of qualified, trained staffing	
7. There is adequate lighting and there are adequate flat surfaces for both running and reading the test kits	
8. The venue is appropriate context for providing preliminary positive results.	
9. Confirmatory specimen collection, transport, and storage system works at this site	
10. Biohazardous waste collection, storage, and transport works at this site.	
11. The site conforms to OSHA/WISHA standards and has the capacity to handle bloodborne pathogen occupational exposures	
12. Members of the priority population remain at the venue long enough to receive counseling, testing, and results.	
13. <i>The venue serves a high-prevalence population ($\geq 1\%$)</i>	
14. <i>There is evidence of substantial under-screening of a high prevalence population</i>	

APPENDIX C: Washington State Requirements (Risk Screening, Testing, and Counseling for Rapid HIV)



1. The evaluation of behavioral risk factors can be based on a self-administered risk assessment conducted by the patient.
2. Behavioral Risk, as defined by the Federal Centers for Disease Control (CDC), includes sexual or needle-sharing exposure to an HIV-infected person, men who have sex with men, unprotected sexual intercourse with multiple partners in the past year, injection drug use, sexual partner of an injection drug user, diagnosis with another STD, a woman having unprotected sexual intercourse with a bisexual man, etc.
3. Other factors can include acute occupational exposure, pregnancy (due to the efficacy of treatment to prevent vertical transmission), etc.
4. Information may be provided verbally or in writing and must include, at minimum, the following: benefits of learning HIV status; the dangers of HIV; how HIV is transmitted and can be prevented; the meaning of HIV test results and the importance of obtaining test results; and, as appropriate, the availability of anonymous HIV testing. A person who has been previously tested may decline receipt of information.
5. The extent of counseling is influenced by the practice setting, the provider/patient relationship, the patient's interest in behavior change and other factors. Referral for counseling to other community providers is permitted, including when the provider lacks counseling skills or time. Required prevention counseling must be based on an assessment of the individual patient's risk; should help the client set realistic behavior change goals that would reduce the risk of transmitting or acquiring HIV; and should create opportunities to build appropriate risk reduction skills.
6. An individual's decision to refuse pretest counseling is not grounds for denying HIV testing.

NOTES



DOH Pub 430-015 Revised 10/2005

For persons with disabilities, this document is available on request in other formats. Please call 1-800-272-2437